PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 8391SG6PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/SG2003/000179**	International Filing Date *(day/month/year)* 30 July 2003	Priority Date *(day/month/year)* 30 July 2002
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61L 27/12, 27/42; C01B 25/32		
Applicant NANYANG TECHNOLOGICAL UNIVERSITY et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheet(s).

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [X] Certain observations on the international application

Date of submission of the demand 9 February 2004	Date of completion of the report 6 August 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **ALBERT S. J. YONG** Telephone No. (02) 6283 2160

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SG2003/000179

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1-7,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **8,** received on **27 July 2004** with the letter of **27 July 2004**

☒ the drawings, pages **1-3,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-3	YES
	Claims	NO
Inventive step (IS)	Claims 1-3	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-3	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The present application appears directed to a method of producing nano-composite powders comprised of hydroxyapatite (HA), reinforced with nano-sized zirconium oxide particles and a composition produced thereof.

The problem to solve appears to reside in providing a method to control the physiological stability of HA in order to promote intimate bone growth (and rapid fixation), the mechanical properties thereof and further prevent decomposition of HA to tricalcium phosphate (TCP).

The following documents are considered most relevant to the present invention;

D1 - JP 07-008550 A

D2 - JP 03-037071 A

D3 - WO 1990/011979 A

D4 - GB 2354519 A

D1 discloses an apatite slurry comprising;

Fine particles (≤ 0.1 micron and ≤ 90% wt) mixed with ZrO_2 powder (≤ 50% wt) passed to a spray dryer by pump, where atomiser attached thereto produces a granulated spray - useful in cosmetics. It appears by virtue of the reactions taking place that trace amounts of calcium phosphate are inherently included in final product. There is no direct disclosure in D1 to RF plasma spraying nor any direct disclosure to the reaction scheme defined in present claim 1.

D2 discloses artificial bone manufacture using a composite comprising an Al_2O_3 and ZrO_2 high strength core coated with a film/powder comprising 99-34% wt HA and 1-66% wt ZrO_2. There is no direct disclosure in D2 to subjecting said coating composition to RF plasma spraying. Furthermore D2 makes no mention of the particle sizes of either the composite coating composition or the components of said composition.

D3 discloses mixing powders of HA + ZrO_2 (15% wt and 85% wt respectively) and traces of TCP to prepare a ceramic composite through hot isotactic pressing (HIP), useful as a dental or orthopaedic implant material. D3 makes mention (page 9) of the particle sizes of HA being < 6μm. but does not disclose using RF plasma spraying to produce nano-composite powders thereof.

International application No.
PCT/SG2003/000179

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D4 discloses the preparation of a porous article by dispersing fine particles in a liquid carrier. Page 4 indicates HA and ZrO_2 in said dispersion where their content broadly ranges from 10-90% wt of each or both and 95% of fine particles in the dispersion are preferably less than 2μm. Page 8 further identifies the material produced from such a dispersion has acceptability in medical applications (eg, bone grafts and dental surgery) - See also page 9, Example 1 and claims 5-7 of D4. There is no disclosure to subjecting the dispersion to RF plasma spraying.

NOVELTY (N) Claims 1-3

The claims of the present invention are considered to be novel over the cited documents since all of the essential features of the independent claim (and appended claims) are not singularly disclosed in the cited references.

INVENTIVE STEP (IS) Claims 1-3

Accordingly, since the subject matter of the claims in the current application is deemed novel, it is considered these claims also contain an inventive step in light of D1-D4. None of the cited references fairly suggest subjecting the claimed composition to RF Plasma spraying in order to form a nano-composite powder.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

- Claim 1 is also not clear with respect to 'subjecting the composite feedstock to RF plasma spraying'. The description at page 4 stipulates the *suspension is then fed axially into induction plasma by a* ***special atomisation probe*** and this step appears to be vital to preparing the nano-composite powders of the present invention. Present claim 1 does not appear to be fully supported by the description through the lack of a special atomisation step in the recited method of said claim.